K061278

## SECTION 6: 510(K) SUMMARY

**510(k) Summary of Safety and Effectiveness as required per 21 CFR 807.92.**
**April 15, 2006**

**(1) Submitter Details:**

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United Kingdom

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**Position**: Chief Executive Officer
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**Date of submission**: April 15, 2006

**(2) Device Name and Classification**

| | |
|---|---|
| Device name: | Optyse™ |
| Device Common Name: | Ophthalmoscope |

**(3) Classification, product code**

| | |
|---|---|
| Class: | II |
| Product Code: | HLJ |
| CFR: 886.1570 | Ophthalmoscope, battery-powered |

**(4) Predicate Device Information**

The device has been compared to the following cleared device:

| Company | Device | 510(k) |
|---|---|---|
| Rudolf Riester GMBH | Uni II | K925756 |

**(5) Device Description**

The Optyse™ is a compact battery-powered handheld direct ophthalmoscope for use by trained personnel for viewing the fundus or the inside of the back of the eye of a patient.

**(6) Intended Use**

The Optyse™ Lens Free Ophthalmoscope is a direct ophthalmoscope intended to be used by trained professionals to examine the fundus or the inside of the back of the eye.

## (7) Technological Characteristics

The Optyse™ is very similar in design to commercially available hand-held ophthalmoscopes including the named predicate device, the Reister Uni II ophthalmoscope (510 (k) # K925756). The Optyse™ and the Uni II are both considered to be pocket sized, simple direct ophthalmoscopes having the same intended use. The viewing systems use similar sources of illumination, are powered by alkaline batteries and provide a reversed image of the patient's retina to the trained personnel. Both kits are provided with simple carrying cases for storage when the ophthalmoscope is not in use.

## (8) Performance Data

### a. *Non-clinical tests*

The Optyse™ has been compared with legally marketed devices and has been tested according to the standards listed below.

***ISO 10942***

Compliance testing of the Optyse™ device to ISO 10942:1998 Ophthalmic Instruments – Direct Ophthalmoscopes has been conducted and a declaration of conformity provided.

***IEC 60601-1***

Compliance testing of the Optyse™ device to IEC 60601-1:1988 Medical Electrical Equipment – Part 1 Requirements for Safety (General) has been conducted and a declaration of conformity provided.

### b. Clinical performance data for equivalence

Clinical trials were not required, however, user studies comparing the effectiveness of the Optyse™ with legally marketed ophthalmoscopes by practising optometrists demonstrated equivalent performance in clarity of view and ability to visualise abnormalities that may be indicative of medical conditions.

**Summary**

The comparison of intended use and technological features of the Optyse™ device with the cleared device taken together with the safety and effectiveness tests and other information in this submission indicate the Optyse™ device is substantially equivalent in safety, effectiveness and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ophthalmos Ltd
c/o Mr. Neil E. Devine
Intertek Testing Services
2307 East Aurora Rd.
Twinsburg, OH 44087

MAY 16 2006

Re: K061278
Trade/Device Name: Optyse™ Ophthalmoscope
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: HLJ
Dated: May 4, 2006
Received: May 8, 2006

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

**Indications for Use**

510(k) Number (if known): K061278 (k)

Device Name: Optyse™ Ophthalmoscope

Indications For Use:

The Optyse™ Lens Free Ophthalmoscope is a direct ophthalmoscope intended to be used to examine the fundus or the inside of the back of the eye

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Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Device Evaluation (ODE)

Denise L. McCarthy

**(Division Sign-Off)**
**Division of Ophthalmic Ear, Nose and Throat Devises**

**510(k) Number** K061278